10/605228 AEC 7/7/10

(e.g., instructions for changes in medication dosage) and/or program instructions for reconfiguring the program included in the cartridge so as to effect changes in the treatment regimen, the analyses or reports to be generated by the healthcare monitoring system, or less important aspects such as graphical presentation presented during the operation of the health care system.

26 AEC 7/7/10

Please amend paragraph ~~31~~ as follows:

26 AEC 7/7/10

[0031] FIG. 1 depicts a self-care health monitoring system arranged in accordance with the invention. In the arrangement shown in FIG. 1 a data management unit 10 is electrically interconnected with a handheld microprocessor-based unit 12 via a cable 14. In the depicted arrangement, data management unit 10 also is electrically interconnected with a blood glucose monitor 16 of the type capable of sensing blood glucose level and producing an electrical signal representative thereof. Although FIG. 1 illustrates blood glucose monitor 16 as being connected to data management unit 10 by a cable 18 it may be preferable to construct blood ~~glucoase~~ glucose monitor 16 as a plug-in unit that is placed in a recess or other suitable opening or slot in data management unit 10. Regardless of the manner in which blood glucose monitor 16 is interconnected with data management unit 10 both that interconnection and cable 14 are configured for serial data communication between the interconnected devices.

27 AEC 7/7/10

Please amend paragraph ~~32~~ as follows:

27 AEC 7/7/10

[0032] Also shown in FIG. 1 are two additional monitoring devices 20 and 22 which are electrically connected for serial data communication with data management unit 10 via cables 24 and 26 respectively. Monitoring units 20 and 22 of FIG. 1 represent devices other than blood glucose monitor 16 that can be used to configure the invention for self-care health monitoring

Please amend paragraph ~~34~~ 29 as follows:

[0034] Another advantage of realizing handheld microprocessor unit 12 in the form of a compact video game system is the relatively simple, yet versatile arrangement of switches that is provided by such a device. For example, as is indicated in FIG. 1 a compact video game system includes a control pad 30 that allows an object displayed on display unit 28 to be moved in a selected direction (i.e., up-down or left-right). As also is indicated in FIG. 1 compact video game systems typically provide two pair of distinctly-shaped push button switches. In the arrangement shown in FIG. 1 a pair of spaced-apart circular push button switches (36 and 38) and a pair of ~~elongate~~ elongated switches (32 and 34) are provided. The functions performed by the two pairs of switches is dependent upon the program instructions contained in each program cartridge 42. Yet another advantage of utilizing a compact video game system for handheld microprocessor-based unit of FIG. 1 is the widespread popularity and low cost of such units. In this regard, manufacture and sale of a data management unit 10 blood ~~glucoase~~ glucose monitor 16 and program cartridge 42 that operate in conjunction with a compact microprocessor-based video allows the self-care health monitoring system of FIG. 1 to be manufactured and sold at a lower cost than could be realized in an arrangement in which handheld unit is designed and manufactured solely for use in the system of FIG. 1. An even further advantage of using a compact video game system for handheld microprocessor is that such video game systems include means for easily establishing the electrical interconnection provided by cable in FIG. 1. In particular, such compact video game systems include a connector mounted to the game unit housing (40 in FIG. 1) and a cable that can be connected between the connectors of two video game units to allow interactive operation of the two interconnected units (i.e., to allow contemporaneous game play by two players or competition between

system operation and obtain desired test results and other information.

Please amend paragraph ~~37~~ 32 as follows:

[00~~37~~32] As is indicated in FIG. 1 data management unit 10 of the currently preferred embodiments of the invention also includes a modem that allows data communication between data management unit 10 and a remote computing facility identified in FIG. ~~1as~~ 1 as clearinghouse 54 via a conventional telephone line 64 (indicated by reference numeral 50 in FIG. 1 and a modem 52 that interconnects clearinghouse 54 and telephone line 50. As shall be described in more detail, clearinghouse computing facility 54 facilitates communication between a user of the system shown in FIG. 1 and his or her healthcare professional and can provide additional services such as updating system software. As is indicated by facsimile machine 55 of FIG. 1, a primary function of clearinghouse 54 is providing the healthcare professional with standardized reports 56, which indicate both the current condition and condition trends of the system user. Although a single facsimile machine 55 is shown in FIG. 1 it will be recognized that numerous healthcare professionals (and hence facsimile machine 55 can be connected in signal communication with a clearinghouse 54. Regardless of whether a compact video game system, another type of commercially available handheld microprocessor-based unit, or a specially designed unit is used, the preferred embodiments of FIG. 1 provide a self-care blood glucose monitoring system in which program cartridge 42 (a) handheld microprocessor unit 12 for displaying instructions for performing the blood glucose test sequence and associated calibration and test procedures; (b) handheld microprocessor unit 12 for displaying (graphically or alphanumerically) statistical data such as blood glucose test results taken during a specific period of time (e.g., a day, week, etc.); (c) handheld

microprocessor unit 12 for supplying control signals and signals representative of food intake or other useful information to data management unit 10; (d) handheld microprocessor unit 12 for simultaneous graphical display of blood glucose levels with information such as food intake; and, (e) handheld microprocessor unit 12 for displaying information or instructions from a healthcare professional that are coupled to data management unit 10 from a clearinghouse 54. The manner in which the arrangement of FIG. 1 implements the above-mentioned functions and others can be better understood with reference to FIGS. 2 and 3. Referring first to FIG. 1 clearinghouse 54 receives data from a plurality of self-care microprocessor-based healthcare systems of the type shown in FIG. 1 with the individual self-care health monitoring systems being indicated in FIG. 2 by reference numeral. Preferably, the data supplied to clearinghouse 54 by each individual self-care health monitoring system consists of "raw data," i.e., test results and related data that was stored in memory circuits of data management unit 10 without further processing by data management unit 10. For example, with respect to the arrangement shown in FIG. 1 blood glucose test results and associated data such as food intake information, medication dosage and other such conditions are transmitted to clearinghouse 54 and stored with a digitally encoded signal that identifies both the source of the information (i.e., the system user or patient) and those having access to the stored information (i.e., the system user's doctor or other healthcare professional).

Please amend paragraph ~~38~~ 33 as follows:

[0038] 33 As shall be recognized upon understanding the manner in which it operates, clearinghouse 54 can be considered to be a central server for the various system users (58 in FIG. 2) and each healthcare professional 60. In that regard, clearinghouse 54

(not shown in FIG. 2). Depending upon the hardware and software arrangement of clearinghouse 54 and selections made by the healthcare professional via computer patient information can be provided to the healthcare professional in different ways. For example, computer 62 can be operated to access data in the form that it is stored in the memory circuits of clearinghouse 54 (i.e., raw data that has not been processed or altered by the computational or data processing arrangements of clearinghouse 54. Such data can be processed, analyzed, printed and/or displayed by computer using commercially available or custom software. On the other hand, various types of analyses may be performed by clearinghouse 54 with the results of the analyses being transmitted to the remotely located healthcare professional. For example, clearinghouse 54 can process and analyze data in a manner identical to the processing and analysis provided by the self-care monitoring system of FIG. 1. With respect to such processing and any other analysis and processing provided by clearinghouse 54 results expressed in alphanumeric format can be sent to computer via telephone line 50 and the modem associated with computer with conventional techniques being used for displaying and/or printing the alphanumeric material for subsequent reference.

34 DEC 7/7/10

34 DEC 7/7/10 Please amend paragraph ~~39~~ as follows:

[0039] The arrangement of FIG. 2 also allows the healthcare professional to send messages and/or instructions to each patient via computer telephone line and clearinghouse 54. In particular, clearinghouse 54 can be programmed to generate a menu that is displayed by computer and allows the healthcare professional to select a mode of operation in which information is to be sent to clearinghouse 54 for subsequent transmission to a user of the system described relative to FIG. 1. This same menu (or related submenus) can be used by the healthcare professional to select one

or more modes of operation of the above-described type in which either unmodified patient data or the results of data that has been analyzed by clearinghouse 54 is provided to the healthcare provider via computer and/or facsimile machine 55. In the currently contemplated arrangements, operation of the arrangement of FIG. 2 to provide the user of the invention with messages or instructions such as changes in medication or other aspects of the healthcare program is similar to the operation that allows the healthcare professional to access data sent by a patient, i.e., transmitted to clearinghouse 54 by a data management unit 10 of FIG. 1 . The process differs in that the healthcare professional enters the desired message or instruction via the keyboard or other interface unit of computer. Once the data is entered and transmitted to clearinghouse 54 it is stored for subsequent transmission to the user for whom the information or instruction is intended.

35 AAC 7/7/10

35 AAC 7/7/10 Please amend paragraph ~~40~~ as follows:

[0040] With respect to transmitting stored messages or instructions to a user of the invention, at least two techniques are available. The first technique is based upon the manner in which operational modes are selected in the practice of the invention. Specifically, in the currently preferred embodiments of the invention, program instructions that are stored in data management unit 10 and program cartridge 42 cause the system of FIG. 1 to generate menu screens which are displayed by display unit 28 of handheld microprocessor unit 12. The menu screens allow the system user to select the basic mode in which the system of FIG. 1 is to operate and, in addition, allow the user to select operational subcategories within the selected mode of operation. Various techniques are known to those skilled in the art for displaying and selecting menu items. For example, in the practice of this invention, one or more main menus can be generated and displayed which allow the system user to

38 AEC 7/7/10

Please amend paragraph ~~43~~ 38 as follows:

[0043] Practicing the invention in an environment in which the healthcare professional uses a personal computer in some or all of the above-discussed ways can be very advantageous. On the other hand, the invention also provides healthcare professionals timely information about system users without the need for a computer (62 in FIG. 2) or any equipment other than a conventional facsimile machine (55 in FIGS. 1 and 2). Specifically, information provided to clearinghouse 54 by a system user can be sent to a healthcare professional 60 via telephone line 68 and facsimile machine 55 with the information being formatted as a standardized graphic or textual report (56 in FIG. ~~1~~ 1). Formatting a standardized report 56 (i.e., analyzing and processing data supplied by blood ~~glucoase~~ glucose monitor 16 or other system monitor or sensor) can be effected either by data management unit 10 or within the clearinghouse 54 facility. Moreover, various standardized reports can be provided (e.g., the textual and graphic displays discussed below relating to FIGS. 6-10) Preferably, the signal processing arrangement included in clearinghouse 54 allows each healthcare professional 60 to select which of several standardized reports will be routinely transmitted to the healthcare professionals' facsimile 55, and, to do so on a patient-by-patient (user-by-user) basis.

39 AEC 7/7/10

Please amend paragraph ~~44~~ 39 as follows:

[0044] FIG. 3 illustrates the manner in which data management unit 10 is arranged and interconnected with other system components for effecting the above-described operational aspects of the invention and additional aspects that are described relative to FIGS. 4-10. As is symbolically indicated in FIG. 3 handheld microprocessor unit 12 and blood ~~glucoase~~ glucose monitor 16 are connected to a dual universal asynchronous receiver transmitter 70 (e.g., by cables 14

circuit (e.g., a metal-oxide semiconductor field-effect transistor circuit), which automatically energizes data management unit 10 whenever any one (or more) of the devices associated with signal sensors 74 is connected to data management unit 10 and is energized. Thus, as is indicated in FIG. 3 by signal path 76 each signal sensor 74 is interconnected with power supply 78 which supplies operating current to the circuitry of data management unit 10 and typically consists of one or more small batteries (e.g., three AAA alkaline cells).

40 AAC 7/7/10

Please amend paragraph ~~45~~ as follows:

40 AAC 7/7/10

[0045] The microprocessor and other conventional circuitry that enables data management unit 10 to process system signals in accordance with stored program instructions is indicated in FIG. 3 by central processing unit (CPU) 80. As is indicated in FIG. ~~3by~~ 3 by interconnection 82 between CPU 80 and battery 78, CPU 80 receives operating current from power supply 78 with power being provided only when one or more of the signal sensors 74 are activated in the previously described manner. A clock/calendar circuit 84 is connected to CPU 80 (via signal path 86 in FIG. ~~3~~ 3) to allow time and date tagging of blood glucose tests and other information. Although not specifically shown in FIG. 3 operating power is supplied to clock/calendar 84 at all times.

41 AAC 7/7/10

Please amend paragraph ~~46~~ as follows:

41 AAC 7/7/10

[0046] In operation, CPU 80 receives and sends signals via a data bus (indicated by signal path 88 in FIG. ~~3~~ 3) which interconnects CPU 80 with dual universal asynchronous receiver transmitters 70 and 72. The data bus 88 also interconnects CPU 80 with memory circuits which, in the depicted embodiment, include a system read-only memory (ROM) 90 a program random access memory (RAM) 92 and an electronically erasable read-only memory (EEROM) 94. System ROM 90

practice of the invention, the procedure is selected from one of the system menus. For example, if the system main menu includes a "monitor" menu item, a submenu displaying system calibration options and an option for initiating the blood glucose test may be displayed when the monitor menu item is selected. When a code strip option is available and selected, a sequence of instructions is generated and displayed by display screen 28 of handheld microprocessor unit 12 to prompt the user to insert the code strip and perform all other required operations. At the conclusion of the code strip calibration sequence, display unit 28 of handheld microprocessor unit 12 displays a message indicating whether or not the calibration procedure has been successfully completed. For example, FIG. 4 illustrates a screen display that informs the system user that the calibration procedure was not successful and that the code strip should be inserted again (i.e., the calibration procedure is to be repeated). As is indicated in FIG. 4 display screens that indicate a potential malfunction of the system include a prominent message such as the "Attention" notation included in the screen display of FIG. 4. As previously indicated, the blood glucose test sequence that is employed in the currently preferred embodiment of the invention is of the type in which a test strip is inserted in a receptacle that is formed in the blood glucose monitor 16. A drop of the user's blood is then applied to the test strip and a blood glucose sensing sequence is initiated. When the blood glucose sensing sequence is complete, the user's blood glucose level is displayed.

42 AAC 7/7/10

Please amend paragraph [0047] as follows:

[0047] In the practice of the invention, program instructions stored in data management unit 10 (e.g., system ROM 90 of FIG. 3) and program instructions stored in program cartridge 42 of handheld microprocessor unit 12 cause the system to display step-by-step

submenu display and the switches of handheld microprocessor 12 to select and enter the appropriate information. A similar menu item--submenu selection process also can be used to enter medication data such as the type of insulin used at the time of the glucose monitoring sequence and the dosage.

Please amend paragraph ~~49~~ as follows:

[0049] The screen display shown in FIG. 8 is representative of statistical data that can be determined by the system of FIG. 1 (using conventional computation techniques) and displayed in alphanumeric format. As previously mentioned, such statistical data and information in various other textual and graphic formats can be provided to a healthcare professional (60 in FIG. 2) in the form of a standardized report 56 (FIG. 1) that is sent by clearinghouse 54 to facsimile machine 55. In the exemplary screen display of FIG. 8 statistical data for blood glucose levels over a period of time (e.g., one week) or, alternatively, for a specified number of monitoring tests is provided. In the exemplary display of FIG. 8, the system (data management unit 10 or clearinghouse 54 also calculates and displays (or prints) the average blood glucose level and the standard deviation. Displayed also is the number of blood glucose test results that were analyzed to obtain the average and the standard deviation; the number of test results under a predetermined level (50 milligrams per deciliter in FIG. 8); and the number of blood glucose tests that were conducted while the user was experiencing hypoglycemic symptoms. As previously noted, in the preferred embodiments of the invention, a screen display that is generated during the blood glucose monitoring sequence allows the user to identify the blood sample being tested as one taken while experiencing hyperglycemic or hypoglycemic symptoms and, in addition, allows the user to specify other relevant information such as food intake and medication information.

48 AEC 7/7/10

Please amend paragraph ~~53~~ 48 as follows:

[0053] It will also be recognized by those skilled in the art that the invention can be embodied in forms other than the embodiments described relative to FIGS. 1-10. For example, the invention can employ compact video game systems that are configured differently than the previously discussed handheld video game systems and palm computers. More specifically, as is shown in FIG. 11, a self-health monitoring system arranged in accordance with the invention can employ a compact video game system of the type that includes one or more controllers 100 that are interconnected to a game console 102 via cable 104. As is indicated in FIG. 11 game console 102 is connected to a video monitor or television 106 by means of a cable 108. Although differing in physical configuration, controller 100, game console 102, and the television or video monitor 106 collectively function in the same manner as the handheld microprocessor 12 of FIG. 1. In that regard, a program cartridge 42 is inserted into a receptacle contained in game console 102 with program cartridge 42 including stored program instructions for controlling microprocessor circuitry that is located inside game console 102. Controller 100 includes a control pad 30 or other device functionally equivalent to control pad 30 of FIG. 1 and switches that functionally correspond to switches 32-38 of FIG. 1. Regardless of whether the invention is embodied with a handheld microprocessor unit 12 (FIG. 1) or an arrangement such as the compact video game system (FIG. 11) in some cases it is both possible and advantageous to apportion the signal processing functions and operations differently than was described relative to FIGS. 1-10. For example, in some situations, the microprocessor-based unit that is programmed by a card or cartridge (e.g., handheld unit 12 of FIG. 1 or compact video game console of FIG. 11) includes memory and signal processing capability that allows the microprocessor to perform all or most of the functions and

operations attributed to data management unit 10 of the embodiments discussed relative to FIGS. 1-10. That is, the digitally encoded signal supplied by blood glucose monitor 16 (or one of the other monitors 20 and 22 of FIG. 1) can be directly coupled to the microprocessor included in game console 102 of FIG. 11 or handheld microprocessor 12 of FIG. 1. In such an arrangement, the data management unit 10 is a relatively simple signal interface (e.g., interface unit of FIG. 11) the primary purpose of which is carrying signals between the blood glucose monitor 16 (or other monitor) and the microprocessor of game console 102 (FIG. 11) or handheld unit 12 (FIG. 1). In some situations, the interface unit may consist primarily or entirely of a conventional cable arrangement such as a cable for interconnection between RS-232 data ports or other conventional connection arrangements. On the other hand, as is shown in FIG. 11 signal interface 110 can either internally include or be connected to a modem 52, which receives and transmits signals via a telephone line 50 in the manner described relative to FIGS. 1 and 2.

Please amend paragraph ~~54~~ as follows:

[0054] It also should be noted that all or a portion of the functions and operations attributed to data management unit 10 of FIG. 1 can be performed by microprocessor circuitry located in blood ~~glucoase~~ glucose monitor 16 (or other monitor that is used with the system). For example, a number of commercially available blood glucose monitors include a clock/calendar circuit of the type described relative to FIG. 3 and, in addition, include microprocessor circuitry for generating visual display signals and signals representative of both current and past values of monitored blood glucose level. Conventional programming and design techniques can be employed to adapt such commercially available units for the performance of the various functions and operations attributed in